



1013 10-1-04

October 29, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5830 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Thank you for your help and patience. I apologize for not being able complete the docket comment / response entry correctly and timely. I appreciate the opportunity to reply in writing.

The Arizona Heart Institute (AHI) has the first physician sponsored IND for Myoblast Cell Implantation via 3-D NOGA imaging catheter based delivery to the heart. While at TCT, Dr. Nabil Dib, MD the Principal Investigator, extended an invitation to Dr. Richard McFarland, PhD, MD and Dr. Stephen Grant, MD. The Arizona Heart Institute would like to participate as a training site for this stem cell technology.

Please advise to the steps necessary to establish a FDA training here at AHI.

Sincerely,

Sue Moravec, PharmD
Vice President of Clinical Research
Arizona Heart Institute

Copy to: Lonnie Warren Myers
Division of Manufacturers Assistance and Training
CBER/FDA (HFM-49)
1401 Rockville Pike
Rockville, MD 20852-1448

2004N-0408

ARIZONA HEART
INSTITUTE

LET

Moravec, Susan

From: Moravec, Susan
Sent: Friday, October 29, 2004 2:07 PM
To: 'Warren-Myers, Lonnie'; Moravec, Susan
Subject: RE: Reg. Site Vist Training Program



FDA Training Site
Request 10_0...

Your copy. Thank you

Sue Moravec, PharmD
Vice President Clinical Research
Arizona Heart Institute
602-266-2200 ext 4196
smoravec@azheart.com

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-----Original Message-----

From: Warren-Myers, Lonnie [mailto:warren_myers@cber.fda.gov]
Sent: Wednesday, October 27, 2004 8:58 AM
To: 'Moravec, Susan'
Subject: RE: Reg. Site Vist Training Program

Since you've been in contact with me I think it is OK to submit in writing.
Go ahead and do that at this address:

cbertrainingsuggestions@cber.fda.gov

Thanks for your interest.

Lonnie

-----Original Message-----

From: Moravec, Susan [mailto:SMoravec@azheart.com]
Sent: Wednesday, October 27, 2004 11:29 AM
To: 'Warren-Myers, Lonnie'; Moravec, Susan
Subject: RE: Reg. Site Vist Training Program

They must have removed 2004N-0408 since it is passed 10-25. Can I submit in writing? Or is it too late.

Sue Moravec, PharmD
Vice President Clinical Research
Arizona Heart Institute
602-266-2200 ext 4196
smoravec@azheart.com

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-----Original Message-----

From: Warren-Myers, Lonnie [mailto:warren_myers@cber.fda.gov]
Sent: Wednesday, October 27, 2004 7:07 AM
To: 'Moravec, Susan'
Subject: RE: Reg. Site Visit Training Program

You should use the docket associated with the site visit training program which is 2004N-0408. You should on that page see a place to go and submit a request to participate. I may not be understanding your question and I am sorry. Call again if needed.

-----Original Message-----

From: Moravec, Susan [mailto:SMoravec@azheart.com]
Sent: Tuesday, October 26, 2004 4:19 PM
To: 'Warren-Myers, Lonnie'; Moravec, Susan
Subject: RE: Reg. Site Visit Training Program

Lonnie,
I left you a voice message. I had problems understanding the site you gave me. Since the request is for Dr. Grant & Dr. McFarland to visit our site to view a procedure, I did not understand which docket to use?

Sue Moravec, PharmD
Vice President Clinical Research
Arizona Heart Institute
602-266-2200 ext 4196
smoravec@azheart.com

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-----Original Message-----

From: Warren-Myers, Lonnie [mailto:warren_myers@cber.fda.gov]
Sent: Monday, October 25, 2004 1:28 PM
To: 'smoravec@azheart.com'
Subject: Reg. Site Visit Training Program

Sue,

Thanks for your interest in the subject program. Please use the following link to see the FR Notice and to submit a request to participate. If you need further assistance, please call.

Thanks again,
Lonnie Warren Myers
Education Specialist

FDA/CBER

Office of Communication, Training, and Manufacturers Assistance

Division of Manufacturers Assistance and Training

301-827-1439 (direct)

<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>

<<http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>

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Dockets Open for Comment

If your comments are **NOT** related to a docket listed below, you can submit written comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

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Dockets Open for Comment

109 Dockets

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Docket ID	Title	Published Date	Comment Period Ends	Submit Comment
2004N-0033	Establishing a Docket regarding the Factor VIII Inhibitor Workshop of November 21, 2003	07/02/04	06/06/06	Go
2003D-0117	Guidance for Industry, FDA Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability	10/04/04	10/04/05	Go
2003D-0382	Final Guidance for Industry on Guidance for Industry, PAT - A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance	10/04/04	10/04/05	Go
2003D-0380	Guidance for Industry: FDA Review of Vaccine Labeling Requirements for Warnings, Use Instructions, and Precautionary Information	10/04/04	10/04/05	Go
2004D-0414	Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems; Availability	10/04/04	10/04/05	Go
2004D-0412	Guidance for Industry: Use of Material from Bovine Spongiform Encephalopathy-Positive Cattle in Animal Feed; Availability	09/29/04	09/29/05	Go
2004D-0438	Immunology and Microbiology Devices; Classification of the Beta-Glucan Serological Assay; Guidance Document; Availability	09/29/04	09/29/05	Go
2004D-0371	Notice of Public Meeting - Novel Formulations of Dialysis Solutions	09/23/04	09/23/05	Go
2004N-0404	Guidance for Industry and Clinical Investigators on the Use of Clinical Holds Following Clinical Investigator Misconduct; Availability	09/10/04	09/15/05	Go
2002D-0320	Draft guidances for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Dental Noble Metal Alloys and Class II	09/01/04	09/01/05	Go
2003D-0391		08/20/04	08/22/05	Go

<u>2003D-0112</u>	Special Controls Guidance Document: Dental Base Metal Alloys; Availability Guidance for Industry on Independent Consultants for Biotechnology Clinical Trial Protocols; Availability	08/19/04	08/19/05	<u>Go</u>
<u>2004D-0361</u>	Guidance for Industry; Prior Notice of Imported Food Contingency Plan for Systems Outages; Availability	08/16/04	08/16/05	<u>Go</u>
<u>2003D-0554</u>	Compliance Policy Guide Sec. 110.310 -	08/12/04	08/16/05	<u>Go</u>
<u>2004N-0330</u>	Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Advisory Committee	07/30/04	07/29/05	<u>Go</u>

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